EURneffy® (adrenaline nasal spray) Approved in the U.K. as the First and Only Needle-Free Emergency Treatment of Allergic Reactions (anaphylaxis)

July 18, 2025

EUR*neffy* (***neffy***® in the U.S.) *offers a new delivery method for adrenaline in the U.K. for adults and children (≥30 kg) living with severe allergic reactions*

ALK-Abelló A/S, which owns the rights to market **EUR*neffy*** *in the U.K., expects availability in late Q3 2025*

U.K. is the largest market outside the U.S. for adrenaline (epinephrine) auto-injector sales

SAN DIEGO, July 18, 2025 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect themselves from allergic reactions that could lead to anaphylaxis, announced today that the United Kingdom (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA) has granted approval for **EUR*neffy*** (adrenaline nasal spray) for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh greater than 30 kg.

"The approval of **EUR*neffy*** marks a major milestone as the first needle-free adrenaline treatment available in the U.K. for adults and children with severe allergies. This innovation addresses a critical need for the many patients who may not carry, or hesitate to use, an injectable option in an emergency," said Richard Lowenthal, Co-founder, President and CEO of ARS Pharma. "The innovative design of **EUR*neffy*** with its small size, temperature stability up to 50°C and longer shelf life compared to auto-injectors, encourages patients and caregivers to always carry and use epinephrine at the first sign of symptoms related to a food or venom allergy reaction. We are pleased to receive this approval and expand availability of our epinephrine nasal spray as part of our partnership with ALK-Abelló A/S."

In November 2024, ARS Pharma entered into an exclusive licensing agreement with ALK-Abelló A/S (Nasdaq: ALK B), granting ALK the rights to commercialize ***neffy*** (epinephrine nasal spray) outside the United States, including Europe (where it is marketed as **EUR*neffy***), Canada, and select other international markets. ARS Pharma retains full commercial rights to ***neffy*** in the U.S., with no changes to its existing partnerships in Japan, China, Australia, and New Zealand. Under the terms of the agreement, ARS Pharma received a $145 million upfront payment in 2024 and is eligible for up to an additional $320 million in regulatory and commercial milestone payments, in addition to tiered double-digit royalties in the teens on net sales in the licensed territories.

neffy is commercially available in the U.S. for the emergency treatment of allergic reactions, including anaphylaxis, in adults and children aged 4 years and older who weigh at least 33 pounds (15 kg). In May 2025, ARS Pharma and ALK initiated a four-year co-promotion agreement aimed at expanding outreach to nearly 20,000 healthcare providers, particularly pediatricians, during the critical back-to-school season, which represents a peak period for epinephrine prescriptions.

In late June, ALK successfully launched **EUR*neffy*** in Germany. Regulatory approvals for ***neffy*** in Canada (with ALK), Japan (in partnership with Alfresa), and Australia (in partnership with CSL), are expected by the end of 2025, with commercial rollouts planned for early 2026. As well, regulatory approval for ***neffy*** in China (in partnership with Pediatrix) is expected in 2026.

EUR*neffy* is the trade name for ***neffy***® (epinephrine nasal spray) in the United Kingdom.

About *neffy*®
neffy is a nasal spray used for emergency treatment of allergic reactions including anaphylaxis, in adults and children aged 4 years and older who weigh 33 lbs. or greater.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR ***neffy*** (epinephrine nasal spray)

INDICATION

neffy is indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients aged 4 years and older who weigh 33 lbs. or greater.

IMPORTANT SAFETY INFORMATION

neffy contains epinephrine, a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life-threatening, can happen in minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or other unknown causes.

Always carry two ***neffy*** nasal sprays with you because you may not know when anaphylaxis may happen and because you may need a second dose of ***neffy*** if symptoms continue or come back. Each ***neffy*** contains a single dose of epinephrine. ***neffy*** is for use in the nose only.

Use ***neffy*** right away, as soon as you notice symptoms of an allergic reaction. If symptoms continue or get worse after the first dose of ***neffy***, a second dose is needed. If needed, administer a second dose using a new ***neffy*** in the same nostril starting 5 minutes after the first dose. Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed after using ***neffy***.

Tell your healthcare provider if you have underlying structural or anatomical nasal conditions, about all the medicines you take, and about all your medical conditions, especially if you have heart problems, kidney problems, low potassium in your blood, Parkinson's disease, thyroid problems, high blood pressure, diabetes, are pregnant or plan to become pregnant, or plan to breastfeed.

Tell your healthcare provider if you take or use other nasal sprays or water pills (diuretics) or if you take medicines to treat depression, abnormal heart

beats, Parkinson's disease, heart disease, thyroid disease, medicines used in labor, and medicines to treat allergies. ***neffy*** and other medications may affect each other, causing side effects. ***neffy*** may affect the way other medicines work, and other medicines may affect how ***neffy*** works.

***neffy* may cause serious side effects. If you have certain medical conditions or take certain medicines, your condition may get worse, or you may have more or longer lasting side effects when you use *neffy*.**

Common side effects of ***neffy*** include: nasal discomfort, headache, throat irritation, chest and nasal congestion, feeling overly excited, nervous or anxious, nose bleed, nose pain, sneezing, runny nose, dry nose or throat, tingling sensation, including in the nose, feeling tired, dizziness, nausea, and vomiting.

Tell your healthcare provider if you have any side effects that bother you or that do not go away after using ***neffy***.

These are not all of the possible side effects of ***neffy***. Call your healthcare provider for medical advice about side effects. To report side effects, contact ARS Pharmaceuticals Operations, Inc. at **1-877-MY-NEFFY (877-696-3339)** or the FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.

Please see the full Prescribing Information and Patient Information for *neffy*.

About Type I Allergic Reactions Including Anaphylaxis
Type I allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine, the only FDA-approved medication for these reactions. While epinephrine auto-injectors have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, over the last three years, approximately 20 million people have been diagnosed and treated for severe Type I allergic reactions that may lead to anaphylaxis, but (in 2023, for example) only 3.2 million filled their active epinephrine auto-injector prescription, and of those, only half consistently carry their prescribed auto-injector. Even if patients or caregivers carry an auto-injector, more than half either delay or do not administer the device when needed in an emergency.

About ARS Pharmaceuticals, Inc.
ARS Pharma is a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis. The Company is commercializing ***neffy***® (trade name **EUR*neffy***® in the EU), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult patients and pediatric patients 4 years of age and older who weigh 15 kg or greater, and in the EU for emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products, and other allergens as well as idiopathic or exercise induced anaphylaxis in adults and children who weigh 30 kg or greater. For more information, visit www.ars-pharma.com.

Forward Looking Statements

Statements in this press release that are not purely historical in nature are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to: the belief that ARS Pharma is well positioned for sustained growth and meaningful value creation; expected benefits from the co-promotion agreement with ALK; the extent to which ARS Pharma's efforts to reach key prescribing pediatricians will be accelerated through the co-promotion agreement prior to the back-to-school season or thereafter; the anticipated timing of regulatory decisions for ***neffy*** in Canada, China, Japan and Australia; the expected timing of commercial launches in the U.K.; the needle-free profile of ***neffy*** increasing the likelihood that patients will both carry and administer epinephrine; the potential market and demand for ***neffy***; and other statements that are not historical fact. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “anticipate,” “believe,” “can,” “could,” “expect,” “if,” “may,” “on track to/for,” “potential,” “plan,” “will,” “would,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharmaceuticals’ current expectations and involve assumptions that may never materialize or may prove to be incorrect.

Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation: potential safety and other complications from ***neffy***; the ability to obtain and maintain regulatory approval for ***neffy*** in its currently approved indications; the scope, progress and expansion of developing and commercializing ***neffy***; the scope, progress and expansion of developing our intranasal epinephrine technology; clinical trial results; the potential for governments and payors to delay, limit or deny coverage for ***neffy***; the size and growth of the market for ***neffy*** and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS Pharma’s’ ability to protect its intellectual property position; and the impact of government laws, regulations and policies. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption “Risk Factors” in ARS Pharma’s Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission (“SEC”) on March 20, 2025, and in ARS Pharma’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on May 14, 2025. These documents can also be accessed on ARS Pharma’s website at www.ars-pharma.com by clicking on the link “Financials & Filings” under the “Investors & Media” tab.

The forward-looking statements included in this press release are made only as of the date hereof. ARS Pharma assumes no obligation and does not intend to update these forward-looking statements, except as required by law. For more information, visit www.ars-pharma.com, and follow us on LinkedIn and X.

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